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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/179,188 10/27/98 SAKURAI

T KAS-125

HM12/1230
FAY SHARPE BEALL FAGAN MINNICH AND MCKEE
104 EAST HUME AVENUE
ALEXANDRIA VA 22301

EXAMINER

NAFF, D	
ART UNIT	PAPER NUMBER

1651

DATE MAILED:

12/30/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/21/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-12 + 16-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 + 16-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, filed 10/21/99

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The amendment of 10/21/99 has been entered. The amendment amended the specification, canceled claims 13-15, amended claims 1-4 and 6-12, and added claims 16-19.

Claims examined on the merits are 1-12 and 16-19 which are all
5 claims in the application.

In regard to foreign patent documents that were lined through on page 1 of form PTO-1449 of 10/27/98, applicants state that these documents correspond to U.S. Patents also cited on the form, and have submitted another form PTO-1449 listing the documents. However, even
10 when corresponding U.S. Patents are cited, copies of the foreign documents must be submitted. The U.S. Patents serve only as a translations, and not as substitutions. It is noted that neither of the U. S. Patents claim priority based on the foreign documents, and there must also be presented evidence that the U. S. Patents correspond to the
15 foreign documents. Furthermore, form PTO-1449 does not list publication dates for the foreign documents.

The proposed changes to the drawings are correcting errors of a typographical nature, and are acceptable.

The text of those sections of Title 35, U.S. Code not included in
20 this action can be found in a prior Office action.

Claims 1-12 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,
25 had possession of the claimed invention.

The specification fails to support washing without heating as now required in the independent claims. The specification not disclosing heating fails to support that heating was intended to be excluded when the application was filed. There is no basis in the specification for
5 selecting heating as a condition to exclude from all other conditions that also can be excluded.

Claims 1-12 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the
10 invention.

Bridging lines 7 and 8 of claim 1 and where recited in the other independent claims, "making the mixture obtained in said mixing step in contact with a" is uncertain as to meaning and scope. This recitation should be changed to -- contacting the mixture obtained in said mixing
15 step with a --. Also, to be clear, in line 9 of claim 1 and where required in other independent claims, "and" before "bondable" should be changed to -- which is --.

Claims 1-12 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al (5,234,809) in view of Seligson et al
20 (4,935,342) for reasons set forth in the previous office action of 7/21/99, and reiterated below.

Boom et al disclose adsorbing nucleic acids to silicon dioxide containing material (col 2, lines 52-60) in the presence of guanidine hydrochloride (col 3, line 63), washing with a salt containing solution
25 and an alcohol containing solution (col 4, lines 20-30).

Seligson et al disclose adsorbing nucleic acids to an ion exchange column, washing with a chloride salt solution and eluting the nucleic acids (see claims). The salt may be sodium chloride.

It would have been obvious to mix a chloride salt with the ethanol
5 solution used for washing by Boom et al to obtain the function of chloride salt for washing as disclosed by Seligson et al. Using a potassium chloride or acetate salt would have been a matter of obvious choice depending on individual preference and convenience.

Applicants urge that washing in claim 1 is carried out with a
10 solution containing acetate without heating whereas Boom et al wash with an ethanol-water solution and acetone and dry by heating to remove the acetone. However, before washing with alcohol and acetone, Boom et al wash with a chaotropic guanidinium-salt-containing washing buffer. Acetate is a well known buffer component, and its use to produce the
15 washing buffer would have been obvious. When washing with the washing buffer, Boom et al do not heat. The present claims do not exclude a second washing step with ethanol and acetone and heating to remove the acetone.

Applicants urge that Seligson et al wash with a chloride salt which
20 results in nucleic acids containing chloride ions, which should be avoided when nucleic acids are to be used in cell-free translation or reverse transcription. However, the present claims do not exclude the presence of a chloride salt, and claim 6 requires washing with a solution of potassium chloride and claim 7 requires washing with a solution of
25 salt.

Applicants point out that claims 6 and 7 require washing with a solution of potassium chloride and salt, respectively. However, washing with a salt is suggested by Seligson et al, and potassium chloride and other salts are common buffer components that would have been obvious to
5 use as components in forming the washing buffer of Boom et al. Furthermore, claim 7 does not exclude the salt being the chaotropic guanidinium salt in the washing buffer of Boom et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**
10 See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of
15 this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the
20 statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on
25 Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

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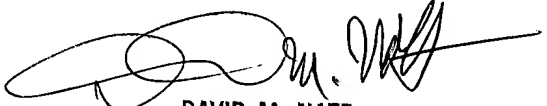
If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
5 (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1285/

DMN
15 12/22/99